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510(k) SUMMARY

Submitter's Name and Address	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
Contact Person	Renuka Krishnan Principal Specialist, Regulatory Affairs (858)503-1815
Common or Usual Name	PTA catheter
Product Code	LIT
Classification	Class II
Proprietary Names	• 1 cm Peripheral Cutting Balloon™ • 2 cm Peripheral Cutting Balloon™ • small Peripheral Cutting Balloon™ Over-the –wire delivery system • small Peripheral Cutting Balloon™ Monorail delivery system

Predicate Devices
Boston Scientific Ultra-Thin Diamond Balloon Dilatation Catheter, K960501
Polarcath™ Peripheral Balloon Catheter system, K030742
CVSi Peripheral Balloon Catheter system, K022061

Device Description
The Peripheral Cutting Balloon™ (PCB) has the features of a conventional angioplasty catheter, with advanced microsurgical capabilities. The PCB features a non-compliant balloon with three or four atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The device is inserted over a guidewire and delivered to the target lesion. Upon inflation, the atherotomes score the plaque as the balloon expands and pushes the plaque radially. The scores serve as notches for stress concentration and allow dilatation at lower pressures, minimizing barotrauma.

Three of the PCB devices (1 cm, 2 cm and sPCB OTW) are offerred in Over-the-Wire delivery configuration, the sPCB is also available in Monorail configuration. The OTW devices are attached to a Y-connector at one end, the sPCB MR is attached to a female luer. The OTW catheters feature a co-axial shaft consisting of an inflation lumen and a guidewire lumen; the sPCB MR features a proximal shaft using a single lumen hypotube, which is attached to a coaxial distal section consisting of an inflation and guidewire lumen. The guidewire exit port for the sPCB MR is 24 cm from the catheter tip.

Table 1. Model Numbers, 1 cm and 2 cm PCB

Device	*Nom. Diameter*	*Catheter Length*		
		50 cms	*90 cms*	*135 cms*
1 cm PCB	5.0 mm	BP505010	BP905010	BP1355010
	5.5 mm	BP505510	BP905510	BP1355510
	6.0 mm	BP506010	BP906010	BP1356010
	7.0 mm	BP507010	BP907010	BP1357010
	8.0 mm	BP508010	BP908010	BP1358010
2 cm PCB	5.0 mm	PCB502050	PCB502090	PCB5020135
	6.0 mm	PCB602050	PCB602090	PCB6020135
	7.0 mm	PCB702050	PCB702090	PCB7020135
	8.0 mm	PCB802050	PCB802090	PCB8020135

Table 2. Model Numbers, sPCB*

Nom. Diameter (mm)	*Over-the-Wire*	*Monorail*
2.00	PCBO2015140	PCBM2015140
2.50	PCBO2515140	PCBM2515140
3.00	PCBO3015140	PCBM3015140
3.50	PCBO3515140	PCBM3515140
4.00	PCBO4015140	PCBM4015140

* Catheter length: 140 cm; blade length: 1.5 cm.

Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. The sPCB devices are coated with Bioslide at the distal section, the 1 cm and 2 cm PCB are coated with MDX 4-4159.

The Rated Burst Pressure (RBP) for all devices is 10 atm. The devices are available in nominal balloon diameters from 2.0 mm to 8.0 mm and blade lengths of 1 cm to 2 cm (Tables 1-2).

Intended Use

The Peripheral Cutting Balloon catheters are recommended for Percutaneous Transluminal Angioplasty of obstructive lesions in synthetic or native arteriovenous dialysis fistulae.

Substantial Equivalence

The Peripheral Cutting Balloon catheters will incorporate a substantially equivalent design, fundamental technology and intended use as those featured in predicate devices.

Performance Testing

Bench testing and biocompatibility testing support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Conclusion

The Peripheral Cutting Balloon catheters have been shown to be Substantially Equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Boston Scientific IVT
c/o Ms. Renuka S. Kristhnan
Principal Specialist, Regulatory Affairs
3574 Ruffin Road
San Diego, CA 92123

Re: K051254
Peripheral Cutting Balloon™
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: May 13, 2005
Received: May 16, 2005

Dear Ms. Krishnan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lichner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051254

Device Name: Peripheral Cutting Balloon™

Indications For Use:

The Peripheral Cutting Balloon™ catheters are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Prescription Use: **Yes** AND/OR Over-The-Counter Use: **No**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of Cardiovascular Devices

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